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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,949	10/04/2004	Gerardo Perez-Camargo	115808-001	3101

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
05/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/509,949	PEREZ-CAMARGO ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-32 and 34-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-32 and 34-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/remarks and amended claims, all filed on 01/17/08 is acknowledged.

Claims 1-28 remain cancelled, claims 29, 34, 38, 39 and 53-55 have been amended and claim 33 has been cancelled.

Claims pending in the prosecution are claims **29-32 and 34-56.**

The rejections made under 35 USC 112.1 and 35 USC 112.2 have been withdrawn in view of amended claims and Applicant's arguments.

The obviousness type double patenting rejection have been withdrawn in view of filing of terminal disclaimer by the Applicants.

The following rejections are necessitated by Applicant's amendments.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 29-32 and 34-56 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,471,999 in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001), (Suzuki et al. Gastroenterology 1999; 116:431-437 7) and (W0 01/62280).

'999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase, taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26). '999 teaches including an alkali in the milk-based powder, which slows the pH, drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects

(col. 4, lines 9-14). '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36). Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats. '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40). '999 teaches omega fatty acids such as soybean oil and in Examples 1-2 (col. 3,
lines 15-20).

'999 does not teach glutathione. However, 571 or 412 teach glutathione. '571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals. '571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41).

Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs

and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).

The references disclosed above do not teach lipid assimilation, however, Simpson et al. disclose that vitamin E is a fat-soluble vitamin that is absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to deficiencies in this and other vitamins, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise its health. (see the entire articles of record).
A skilled artisan would thus have been motivated to provide a pet with an edible composition comprising liver function promoter in order to help in lipid assimilation which in turn helps in improving vitamin E absorption with a reasonable expectation of success based on the teachings of the disclosed references.

'999 reference above teaches the pancreatic function promoter (lipase) and intestinal mucosa function promoter such as probiotic microorganism, however, does not correlate the same with lipid absorption. Suzuki et al. disclose that bacterial or porcine Lipase with high or low fat diets optimize fat absorption (see the entire article of record). It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate pancreatic function promoter and intestinal mucosa function promoter in a feed composition and improve lipid absorption capacity

of a pet animal with a reasonable expectation of success. WO correlates the lipid absorption capacity with vitamin E absorption. As such, the pancreatic function promoter would have improved vitamin E absorption with the enhanced absorption of lipid in a pet animal in view of WO.

A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet animal. Since the combination of references teach increased lipid absorption due to intestinal, pancreatic and liver function promoter, it is the position of the examiner that the gut function benefits to the pet is associated with the nutritional composition taught by the prior art.

4. Claims 29-32 and 34-56 are rejected 35 U.S.C. 103(a) as being unpatentable over US Patent No. Fuchs et al WO 02/15719 ('719) in view of US 5,290,571 ('571) or US 5,451,412 ('412) and further in view of (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001), (Suzuki et al. Gastroenterology 1999; 116:431-437 7) and (W0 01/62280).

'719 discloses a method of treatment which comprises administering an effective amount of the composition which contains whey protein (an intestinal mucosa function promoter according to applicant) to improve, promote, maintain intestinal function and mucins a patient or companion animal (abstract, claims 1-2 and 14-20, pg. 6 lines 5-10;

pg. 12 lines 3-21). Example 4 teaches a nutritional supplement comprising whey protein and probiotic bacteria. '719 teaches that the nature of whey protein and the fact that it is capable of being easily digested, the composition has a beneficial effect in patients with limited appetite due illness, surgery, chronic gastritis, etc (pg. 4, line 31-pg. 5, line 6), and that the addition of a probiotic micro-organism provides the advantage of restoring the natural balance of the intestinal flora following antibiotic therapy (pg. 6, lines 7-10). Whey protein is taught by applicant to be a fat transportation aid agent and carrier (instant spec pg. 10, 13-20). , '719 also teaches including a prebiotic (claim 13, pg. 5, lines 27-30). '719 teaches including taurine and vitamins (claim 12, pg. 5, lines 18-25; pg. 6, lines 27-29), '719 teaches a lipid source including omega-3 fatty acids (abstract, claim 1). , '719 teaches a nutritional supplement comprising whey protein and omega-3 fatty acids (abstract, claims 1-2).

'719 does not teach glutathione. However, 571 or 412 teach glutathione. '571 or '412 teach a composition of whey protein concentrate (abstract). '412 claims 1 and 2 teach compositions containing whey protein concentrate that promote glutathione as nutritional supplements to animals.

'571 teaches that a suitable source of whey protein is known by the trademark PROMOD, which contains whey protein and soy lecithin (col. 5, lines 34-41).

Soy lecithin is taught by applicant in instant Example 2 to be an appropriate liver function promoter. '571 teaches that glutathione GSH promotion is a major function of the whey protein concentrate (w.p.c.) (col. 1, lines 30-37). '571 teaches the production of glutathione in the spleen, heart, liver is greater in mice fed with w.p.c, than mice fed

with egg white protein (col. 4, lines 39-46). '571 teaches that the object of the invention is to provide a method for increasing the concentration level of glutathione in the organs and enhancing resistance to bacterial infection of mammals through the use of w.p.c, via oral administration (col. 10, lines 46-57). '571 also teaches inclusion of vitamins B1 and B2 with w.p.c. (claim 1-3, col. 11, lines 55-57).

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the invention was made to incorporate pancreatic function promoter and intestinal mucosa function promoter in a feed composition and improve lipid absorption capacity of a pet animal with a reasonable expectation of success. WO correlates the lipid absorption capacity with vitamin E absorption. As such pancreatic function promoter would have improved vitamin E absorption with the enhanced absorption of lipid in a pet animal in view of WO.

A skilled artisan would thus have been motivated to formulate a composition comprising liver function promoter, pancreatic function promoter and intestinal function promoter with a reasonable expectation of success in order to help increase lipid absorption and vitamin E absorption of a pet animal. Since the combination of references teach increased lipid absorption due to intestinal, pancreatic and liver function promoter, it is the position of the examiner that the gut function benefits to the pet is associated with the nutritional composition taught by the prior art.

Response to Arguments

5. Applicant's arguments with respect to claims 35, 37-52 and 54-68 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612